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6 **IN THE UNITED STATES DISTRICT COURT**
7 **FOR THE DISTRICT OF ARIZONA**

8 **IN RE: BARD IVC FILTERS**
9 **PRODUCTS LIABILITY LITIGATION,**

MDL No. 2641

10 CASE MANAGEMENT ORDER
11 NO. 7

12 (Stipulation and Order Concerning
13 Redactions of Material from Additional
14 Adverse Event Reports, Complaints, and
15 Other Documents)

16 In accordance with the Stipulation of the Parties and to protect the confidential
17 information of non-parties,

18 **IT IS ORDERED** as follows:

19 The Defendants anticipate producing additional and updated adverse event reports
20 and complaint files maintained pursuant to 21 U.S.C. § 360i, 21 C.F.R. § 803.18, and 21
21 C.F.R. § 820.1 - .250 as well as documents relating to those adverse events and
22 complaints files. To the extent that Defendants are able to identify whether these reports
23 and complaint files relate to a particular named Plaintiff at the time they are produced in
24 this litigation, the parties and their attorneys have consented to and agreed that the
25 Defendants shall refrain from redacting the following identifiable information, as defined
26 in 21 C.F.R. § 20.63(f), in the below three circumstances:

27 (1) Identifiable information of a Plaintiff in this litigation shall not be redacted,
28 pursuant to 21 C.F.R. § 20.63(f)(1)(iii);

- (2) Identifiable information of a Plaintiff in litigation pending in other state or federal courts shall not be redacted, pursuant to 21 C.F.R. § 20.63(f)(1)(iii), if the attorney or law firm representing that Plaintiff is of record in this multi-district proceeding and the other litigation involves a personal injury claim regarding any of Bard's inferior vena cava (IVC) filters unless, prior to production by Defendants, counsel of record for a particular plaintiff requests in writing to counsel for Defendants redaction in accordance with the agreed redaction protocol attached as Exhibit A to this Order;
- (3) Identifiable information of a voluntary reporter shall not be redacted, pursuant to 21 C.F.R. § 20.63(f)(1)(i), where the reporter is an attorney from any of the law firms of record in this multi-district litigation proceeding.

Otherwise, in accordance with 21 CFR § 20.63(f) and other applicable laws, statutes, and regulations, the Defendants shall only redact such information as is set forth in the agreed protocol attached to this Order as Exhibit A, and Plaintiffs shall have the right to object to any redactions made.

The parties acknowledge that this Stipulated Order is intended to and does satisfy the written consent requirement of the federal regulations.

Any documents containing any reporter or personal identifying information shall be designated and branded as confidential in accordance with the protective order entered in this case.

This Order shall govern all cases transferred, filed, or pending in the above-captioned litigation.

Dated this 5th day of January, 2016.

Daniel G. Campbell

David G. Campbell
United States District Judge

EXHIBIT A

Redaction Protocol for Bard Complaint Files

1) Redactions under the Health Insurance Portability Act of 1996 (HIPAA) and under 21 CFR 20.63, redact the following:

Redact the following for the patient, relatives, household members, or employers:

- (1) Names
 - Names of the individuals associated with the corresponding health information (i.e., the subjects of the records) and of their relatives, employers, and household members are redacted. Do not redact doctors, nurses, etc. for HIPAA.
- (2) County, City and Street address and last two digits of zip code
 - DO NOT REDACT COUNTRY, STATE, OR FIRST THREE DIGITS OF ZIP CODE.
 - Washington, DC is considered a state for HIPAA redaction purposes.
- (3) Birthdates and dates of death
 - DO NOT REDACT THE YEAR
- (4) Telephone numbers
- (5) Fax numbers
- (6) Email addresses
- (7) Social security numbers (even if it is only a portion, or the full number but most is X'd out – redact it all)
- (8) Medical record numbers, Accession Numbers, EMR (Electronic Medical Record Number), PHR (Personal Health Record), PMR (Personal Medical Record), Clinical Trial Record Numbers
- (9) Health plan beneficiary numbers, Group Policy IDs, Policy Numbers, etc. (but not the name or address of insurance companies)
- (10) Account numbers
- (11) Certificate/license numbers
- (12) Vehicle identifiers (license plate numbers, VINs, etc.)

- (13) Serial numbers of devices
- (14) URLs, folder paths, file locations if they include patient identifying information or the patient's employer
- (15) IP Addresses if they belong to the patient or the patient's employer
- (16) Biometric identifiers such as fingerprints, patient chart barcodes
- (17) Full face images (not side profiles)
- (18) Any other unique identifier
 - This can include anything that is unique enough to identify the person "President of the United States", "current Provost of the University of Tennessee", "first man to walk on the moon", "first heart transplant recipient"

NOT REDACTED:

- Bard Complaint IDs
- Information about a person who has been dead 50 years or more
- Autopsy reports

2) Redactions of Reporter Information - 21 CFR 20.63

The names, address (including city, state, and country), of any reporter (except if it is a Bard Employee or FDA representative), including the names of

- (1) Names of any doctor, nurse, intern, or employee of the reporter institution. This includes initials.
- (2) Name of the hospital/institution.
- (3) All geographic information including city, state, country, zip code, etc.
- (4) Phone numbers, fax numbers, or pager numbers for the institution, doctor, etc.
- (5) Email addresses, websites for the hospital, etc.
 - Bard Employees are not redacted because not considered voluntary reporters
 - If reporter is an attorney or law firm subject to parties' stipulation regarding redaction, do not redact the attorney/law firm as the reporter.